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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,289	02/20/2007	Atsushi Muraguchi	2870-0330PUS1	9388

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EXAMINER

HOBBS, MICHAEL L

ART UNIT	PAPER NUMBER
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1797

NOTIFICATION DATE	DELIVERY MODE
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09/10/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/573,289	Applicant(s) MURAGUCHI ET AL.	
	Examiner MICHAEL HOBBS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 29-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-26 and 29-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>08/18/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/10/2010 has been entered.

2. Claims 23-26 and 29-30 are pending further examination upon the merits. Claims 1-22 have been withdrawn from consideration due to being drawn to a non-elected invention.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

4. The information disclosure statement filed on 08/10/2010 has been considered by the examiner.

Response to Amendment

5. The declaration under 37 CFR 1.132 filed 08/10/2010 is insufficient to overcome the rejection of claim 23 based upon Bhatia and Griffith under 35 USC 103(a) as set forth in the last Office action because: applicant asserts in the declaration that the use of the fluorocarbon coating results in the unexpected result of the cells not adhering to the walls of the micro-well. To support this result, the applicant presents data relating to the effectiveness of the coating when applied to micro-wells versus micro-wells without the coating (see, for example, table 2 on page 5 of the declaration). This is not found persuasive as the use of a coating to prevent cell adhesion is not unexpected since the coating used is a hydrophobic polymer and should allow for a higher collection rate over a non-coated well. Furthermore, there is no indication that this provides any unexpected results over other hydrophobic coatings or layers such as silanized silicon.

6. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (US 2005/0112033 A1) (will be referred to as '033) in view of Want et al. (US 2003/0032002 A1) (will be referred to as '002).

11. Zhang discloses a multi-well container that discloses the following limitations for claim 23:

“A micro-well array made of silicon and having multiple micro-wells”: '033 discloses a multi-well container ([0007]) and that the multi-well containers are fabricated from silicon ([0066]).

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“each micro-well being used to store a single specimen organic cell and to recover the stored single specimen organic cell therefrom”: This limitation is drawn to the intended use of the claimed device and as such does not provide a structural limitation that defines over the prior art (see also MPEP 2114).

“wherein the interior surface of said micro-wells is coated with a fluorocarbon film”: '033 further discloses that the wells are coated with a non-adsorbing and/or a non-reactive surface such as TEFLON™ ([008]; [0067]) where TEFLON™ is a fluorocarbon.

“so that the interior surface of said micro-wells prevents adhesion of the organic cell and facilitates recovery of the stored organic cell from the micro-well”: This limitation is being interpreted as the intended use of the claimed wells and the wells of '033 are of a size and shape to hold just one organic cell (see also MPEP 2114).

“wherein each micro-well is of a size and shape holding just one organic cell”: While the applied reference of '033 is capable of holding just one organic cell, the reference discloses that the plate can have up to 1536 wells which implies that the well can be sized such that it only holds one cell, but '033 does not explicitly state that the wells are sized as such.

12. '002 discloses a microtiter plate for the isolation and screening of cells that includes using a microtiter plate with either 96, 384m 768 or 1536 wells ([0043]) where this plate is being interpreted as a chip. For claim 23, the wells (micro-well portion 52) of '002 are dimensioned such that they permit only one cell to settle into the well

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([0043]). The wells have a depth of about 20 microns and a diameter of about 20 microns ([0043]).

13. Therefore, it would have been obvious for one of ordinary skill in the art to employ the dimensions suggested by '002 within '033 in order to have micro-wells that can hold only one cell. The suggestion for doing so at the time would have been in order to isolate and detect the desired biological activity of the cell ([0043]; Abstract).

14. For claim 24, '033 discloses that the wells can have a shape such as a regular n-sided polygon, an irregular n-sided polygon, a triangle, a square, a rounded square or a circle ([0060]) to name a few.

15. '033 differs regarding the limitations of claim 25.

16. '002 discloses a microtiter plate for the isolation and screening of cells that includes using a microtiter plate with either 96, 384 or 1536 wells ([0043]) where this plate is being interpreted as a chip. For claim 25, the wells (micro-well portion 52) of '002 are dimensioned such that they permit only one cell to settle into the well ([0043]). The wells have a depth of about 20 microns and a diameter of about 20 microns ([0043]). This range is being interpreted as the well have a diameter that 0.5 to 2-fold the diameter of an organic cell and 0.5 to 4-fold the diameter of a cell with regards to the depth of the well.

17. Therefore, it would have been obvious for one of ordinary skill in the art to employ the dimensions suggested by '002 within '033 in order to have micro-wells that can hold only one cell. The suggestion for doing so at the time would have been in order to isolate and detect the desired biological activity of the cell ([0043]; Abstract).

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18.

19. With regards to claim 26, the organic cell being a lymphocyte is drawn to a material worked upon by an apparatus and does not provide a structural limitation over the prior art (see MPEP 2115). Also, the device being used to detect single antigen-specific lymphocytes is drawn to the intended use of the claimed device and does not provide a structural limitation over the prior art as well as including material worked upon by an apparatus with regards to the antigen-specific lymphocytes (see MPEP 2114 and 2115).

20. Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (US 2005/0112033 A1) (will be referred to as '033) in view of Want et al. (US 2003/0032002 A1) (will be referred to as '002) and in further view of Hunter et al. (US 2004/0191924 A1) (will be referred to as '924).

21. With regards to claims 29 and 30, '033 and '002 differ from the instant claim regarding a hydrophobic region on the surface of the chip surrounding the well.

22. '924 discloses a through-hole array where the substrate is made of silicon and the surface of the substrate is treated to make the top and bottom face hydrophobic ([0079]). For claims 29 and 30, the silicon surface has been treated by oxidation to form silicon oxide surface with high energy. This surface is made hydrophobic by exposing the surface to an appropriate silanizing agent ([0079]). This produces hydrophobic regions around each well which fluidly isolates adjacent wells.

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23. Therefore, it would have been obvious for one of ordinary skill in the art to employ the conventional hydrophobic surface as suggested by '924 within '033 and '002 in order to fluidly isolate each well. The suggestion for doing so at the time would have been in order to retain fluid in each cell ([0078]).

24. With regards to claim 31, '033 and '002 differ from the instant claim regarding a hydrophobic region on the surface of the chip surrounding the well. It should be noted that '033 and '002 discloses the array chip as was discussed for claim 23.

25. '924 discloses a through-hole array where the substrate is made of silicon and the surface of the substrate is treated to make the top and bottom face hydrophobic ([0079]). For claims 31, the silicon surface has been treated by oxidation to form silicon oxide surface with high energy. This surface is made hydrophobic by exposing the surface to an appropriate silanizing agent ([0079]). This produces hydrophobic regions around each well which fluidly isolates adjacent wells.

26. Therefore, it would have been obvious for one of ordinary skill in the art to employ the conventional hydrophobic surface as suggested by '924 within '033 and '002 in order to fluidly isolate each well. The suggestion for doing so at the time would have been in order to retain fluid in each cell ([0078]).

Response to Arguments

27. Applicant's arguments with respect to claims 23-26 and 29-31 have been considered but are moot in view of the new ground(s) of rejection.

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28. Applicant's remarks begin on page 8 and continue to page 11.

29. In the first and second paragraphs on page 8, applicant summarizes the amendments made to the claims and where support can be found for the claim amendments.

30. In the third and fourth paragraphs on page 8, applicant discusses the rejection under 35 USC 102(e) of claim 31 as being unpatentable over the previously applied reference of Reed. It should be noted that applicant's amendment overcomes this rejection.

31. Applicant's traversal of the 35 USC 103(a) rejection begins on the bottom of page 8.

32. In the first and second paragraphs on page 9, applicant summarizes the previous rejection.

33. In the third paragraph on page 9, applicant discusses the claimed invention.

34. Stating on the bottom of page 9 and continuing to page 10, applicant argues that the limitation "wherein the interior surface of said micro-wells is coated with a fluorocarbon film so that the interior surface of said micro-well prevents adhesion of the organic cell and facilitates recover of the stored organic cell of the micro-well" is not functional as it provides a structural element that defines over the claim. While the fluorocarbon coating provides a structural element, the recitation of this coating, the use of this coating to prevent cell adhesion does not provide a structural distinction over the prior art. With regards to giving this limitation "patentable weight", it should be noted that this limitations was examined and considered, but "while features of an apparatus

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may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function" (*In re Schreiber*, 125 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-31 (Fed. Cir. 1997)).

Therefore, this limitation does not structurally define the claimed invention over the prior art.

35. The arguments regarding the applied references of Bhatia and Griffith are moot since these rejections have been withdrawn and the unexpected results presented by applicant have already been addressed.

Conclusion

36. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/M. H./
Examiner, Art Unit 1797